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EXAMINER	
TONGUE, LAKIA J	
ART UNIT	PAPER NUMBER
1645	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,042	INGER MATTSBY-BALTZER	
	Examiner	Art Unit	
	LAKIA J. TONGUE	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 8-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/12/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on November 12, 2008 is acknowledged. Claims 1-28 are pending. Claim 6 has been amended. Claims 6 and 7 are currently under examination.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on November 12, 2008 is in compliance with the provisions of 37 CFR 1.97 and has been considered. An initialed copy is attached hereto.

Objections Withdrawn

2. In view of Applicant's amendment, the objection to claim 6 for misspelling "simultaneous" is withdrawn.

Rejections Maintained

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. The rejection of claims 6 and 7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for the reasons set forth in the previous Office action.

Applicant argues that:

1) The language of claim 6 as filed meets the requirements of paragraph 6 of Section 112 and clearly and directly expresses "a means or step for performing a specified structure" as required.

Applicant's arguments have been fully considered and are deemed non-persuasive.

With regard to Point 1, the Examiner would like to acknowledge Applicant's attempt to amend claim 6 to meet the requirement of paragraph 6 of Section 112, however 'a sampling means for drawing a sample from a patient' lacks the structure which performs the function. The claims are rejected because there is no disclosure of structure, material or acts for performing the claimed function. The recitation, 'an assay means for an assay for the detection of a combination ....' fails to meet the requirements under said statute because Applicant failed to clearly link or associate the disclosed structure, material or acts to the claimed function. Moreover, said recitation fails the third prong of the test, which recites "the phrase "means for" or "step for" *must not* be modified by sufficient structure, material, or acts for achieving the specified function.

As previously presented, regarding claim 6, the word "means" is preceded by the word(s) "for drawing a sample from a patient" and " means for an assay" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The rejection of claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Hayette et al. (Journal of Clinical Microbiology, 1992; 30(2): 411-417), Wakshull et al. (U.S. 2001/0051717 1) and Kanbe et al. (Clinical and Diagnostic Laboratory Immunology, 1996; 3(6): 645-50) is maintained for the reasons set forth in the previous Office action.

Applicant argues that:

1) No significantly increased IgM antibody levels were observed for any of the antigens suggesting that the *C. albicans* infection was not a first time challenge.

2) Wakshull et al. teach methods of isolating β(1-3)-glucan or organisms containing it, and not methods according to the inventions herein.

3) The antigen used and the subtype of the *C. albicans* antibody to be detected in Kanbe et al. is different from the invention herein.

Applicant's arguments have been fully considered and are deemed non-persuasive.

The rejected claims are drawn to a kit for the diagnosis of candidiasis or invasive candidiasis comprising: 1) a sampling means for drawing a sample from a patient; 2) means for an assay for the detection of a combination of an IgG2 antibody to a

phosphopeptidomannan (PPM) fraction of the cell wall of *C. albicans*, and an IgG1 antibody to a *C. albicans* cell wall antigen, and glucan utilizing a coating of *Candida* antigens to test for the IgG2 antibody and the IgG1 antibody, wherein said sample is analyzed for the presence of the simultaneous presence of an IgG2 antibody to a PPM fraction of the cell wall of *C. albicans*, and an IgG1 antibody to a *C. albicans* cell wall antigen, and glucan.

With regard to Points 1 and 2, the claims are drawn to a kit. The prior art discloses the components of the kits, thus rendering the instant invention obvious.

With regard to Point 3, Kanbe et al. was used in combination with Hayette et al. and Wakshull et al. solely to demonstrate the ability to detect *C. albicans* cell wall proteins. The combination of references renders the instant invention obvious.

As previously presented, Hayette et al. disclose a method of detecting the presence of antibodies directed against *C. albicans* O-linked oligomannosides and phosphopeptidomannan in patient sera via an ELISA (see abstract).

Wakshull et al. disclose methods for assaying the presence of glucans as an indicator of Candida infection (see abstract and paragraph 0017 and 0077).

Kanbe et al. disclose a method of detecting *C. albicans* cell wall protein (see abstract and page 645).

Since, Hayette et al., Wakshull et al. and Kanbe et al. disclose analogous inventions related to diagnosis of candidiasis, it is *prima facie* obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea

of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980).

With regard to the specific antibodies recited in claim 6, it is deemed in absence of evidence to the contrary, that the disclosed antigens would bind to all antibody types.

It would be obvious for one of ordinary skill in the art at the time of the invention to place the reagents and components of Hayette et al., Wakshull et al. and Kanbe et al. into a diagnostic test kit in order to take advantage of the reduced cost and increase ease of use associated with kits. It would have been expected, barring evidence to the contrary, that the kit would be effective for the diagnosis of candidiasis or invasive candidiasis.

Moreover, it would have been expected, barring evidence to the contrary, that the composition would be effective in the diagnosis of candidiasis or invasive candidiasis because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention (KSR International Co. v. Teleflex inc., 500 U.S.-, 82 US{Q2d 1385 (2007). Moreover, KSR forecloses the argument that a **specific** teaching, suggestion, or motivation is required to support a finding of obvious. See the recent Board decision *Ex parte Smith,--USPQ2d--,* slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR, 82 USPQ2d* at 1396).

Lastly, since glucan is in several organisms using two distinct antigens from the cell wall of yeast would not only help to eliminate false positives, but would also make

for a more sensitive and specific diagnosis. Moreover, since there are only 4 serogroups for immunoglobulin G, picking IgG1 would simply be a matter of design choice.

5. The rejection of claims 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over Sendid et al. (J. Med. Microbiol, 2002; 51(5): 433-442), Wakshull et al. (U.S. 2001/0051717 1) and Kanbe et al. (Clinical and Diagnostic Laboratory Immunology, 1996; 3(6): 645-50) is maintained for the reasons set forth in the previous Office action.

Applicant argues that:

1) Nothing in Sendid et al. teaches or suggests testing for the particular antibodies plus glucan as set forth in claim 6.

2) Even if Sendid et al. is combined with Wakshull et al. and Kanbe et al. there is no teaching that means for performing these three assays can be combined in a kit.

Applicant's arguments have been fully considered and are deemed non-persuasive.

The rejected claims are drawn to a kit for the diagnosis of candidiasis or invasive candidiasis comprising: 1) a sampling means for drawing a sample from a patient; 2) means for an assay for the detection of a combination of an IgG2 antibody to a phosphopeptidomannan (PPM) fraction of the cell wall of *C. albicans*, and an IgG1 antibody to a *C. albicans* cell wall antigen, and glucan utilizing a coating of *Candida* antigens to test for the IgG2 antibody and the IgG1 antibody, wherein said sample is analyzed for the presence of the simultaneous presence of an IgG2 antibody to a PPM

fraction of the cell wall of *C. albicans*, and an IgG1 antibody to a *C. albicans* cell wall antigen, and glucan.

With regard to Point 1, Sendid et al. disclose diagnosis of systemic candidosis based on the combination of two enzyme immunoassays that detect a candida oligomannoside and antibodies against *C. albicans* mannan (PPM), which is the major cell-wall immunogen in which this epitope is present. Moreover, Sendid et al. disclose that sera are selected from intensive care patients with clinically suspected systemic candidosis. Contrary to Applicant's assertion, the antibodies as set forth in claim 6 are necessarily present for the diagnosis of candidiasis and in absence of evidence to the contrary, the disclosed antigens would bind to all antibody types.

With regard to Point 3, contrary to Applicant's assertion, Sendid et al., Wakshull et al. and Kanbe et al. disclose analogous inventions related to diagnosis of candidiasis, it is *prima facie* obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980).

As previously presented, Sendid et al. disclose diagnosis of systemic candidosis based on the combination of two enzyme immunoassays that detect a candida oligomannoside and antibodies against *C. albicans* mannan (PPM), which is the major cell-wall immunogen in which this epitope is present. Moreover, Sendid et al. disclose

that sera are selected from intensive care patients with clinically suspected systemic candidosis (see abstract).

Wakshull et al. disclose the generation of monoclonal antibodies to glucan. Wakshull et al. disclose that plasma samples were collected and assayed for the presence of antibodies to β(1-3)-glucan by direct ELSIA screen protocol (see paragraph 0077).

Kanbe et al. disclose a method of detecting *C. albicans* cell wall protein (see abstract and page 645).

Since, Sendid et al., Wakshull et al. and Kanbe et al. disclose analogous inventions related to diagnosis of candidiasis, it is *prima facie* obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850,205 USPQ 1069, 1072 (CCPA 1980).

With regard to the specific antibodies recited in claim 6, it is deemed in absence of evidence to the contrary, that the disclosed antigens would bind to all antibody types.

It would be obvious for one of ordinary skill in the art at the time of the invention to place the reagents and components of Sendid et al., Wakshull et al. and Kanbe et al. into a diagnostic test kit in order to take advantage of the reduced cost and increase ease of use associated with kits. It would have been expected, barring evidence to the contrary, that the kit would be effective for the diagnosis of candidiasis or invasive candidiasis.

Moreover, it would have been expected, barring evidence to the contrary, that the composition would be effective in the diagnosis of candidiasis or invasive candidiasis because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention (KSR International Co. v. Teleflex inc., 500 U.S.-, 82 US{Q2d 1385 (2007). Moreover, KSR forecloses the argument that a **specific** teaching, suggestion, or motivation is required to support a finding of obvious. See the recent Board decision *Ex parte Smith,--USPQ2d--*, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR, 82 USPQ2d* at 1396).

Lastly, since glucan is in several organisms using two distinct antigens from the cell wall of yeast would not only help to eliminate false positives, but would also make for a more sensitive and specific diagnosis. Moreover, since there are only 4 serogroups for immunoglobulin G, picking IgG1 would simply be a matter of design choice.

Conclusion

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAKIA J. TONGUE whose telephone number is (571)272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/
Supervisory Patent Examiner,
Art Unit 1645

LJT
2/17/09